K133242

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FEB 14 2014

Section 8 –510(k) Summary

1. General Information

Submitter:	Contact Person:
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Summary Preparation Date: October 17, 2013

2. Names

Device Name(s): Stellaris® Vision Enhancement System

Classification Name(s): Phacofragmentation Unit, Vitreous Aspiration and Cutting Instrument

Common Name: Ophthalmic surgical system for cataract and vitreo-retinal surgery

CFR References: 21 CFR 886.4670, 21 CFR 886.4150

Product Codes: HQC, HQE

3. Predicate Devices

- K082473 – Stellaris® Microsurgical System
- K063331 – Stellaris ® Microsurgical System
- K101325 – Stellaris ® PC Vision Enhancement System

4. Product Description

The Bausch & Lomb Stellaris® Vision Enhancement System is an integrated ophthalmic microsurgical system designed for use in anterior segment surgery including phacofragmentation and vitreous aspirating and cutting- anterior vitrectomy.

The system is based on the technology and the performance of the existing Stellaris® system, and this special 510(k) incorporates software revisions and minor hardware changes. There is no change in the intended use or indications for use of the system.

5. Indications for Use

Indications for Use (same as K082473):

The Bausch & Lomb Stellaris® Vision Enhancement System is intended for the emulsification and removal of cataracts, anterior and posterior segment vitrectomy. The system is designed for use in both anterior and posterior segment surgeries. It provides capabilities for phacoemulsification, irrigation/aspiration, bipolar, coaxial, and bipolar coagulation, vitrectomy, viscous fluid injection/removal and air/fluid exchange operations. Use only Bausch & Lomb disposable packs and handpieces designated for use with the system.

6. Summary of Technological Characteristics

The technological characteristics of the Stellaris Microsurgical system are substantially equivalent to those of the predicate device.

Characteristic	Stellaris® Vision Enhancement System	K082473/K063331 Stellaris® Microsurgical System
Product Code Regulation	HQC, HQE 21 CFR 886.4670, 21 CFR 886.4150	HQC, HQE 21 CFR 886.4670, 21 CFR 886.4150
Intended Use	Intended for use in ophthalmic procedures	Intended for use in ophthalmic procedures
Indications for Use	Exactly the same as K082473	See K082473
User interface	LCD touch screen	LCD touch screen
Device activation	footswitch	footswitch
Electrical requirements	90-130 VAC, 50/60 Hz 200-240 VAC, 50/60 Hz	90-130 VAC, 50/60 Hz 200-240 VAC, 50/60 Hz

7. Safety and Effectiveness Information

The review of the indications for use and technical characteristics provided demonstrates that the Stellaris® Vision Enhancement System is substantially equivalent to the predicate device and is safe and effective for the emulsification and removal of cataracts, anterior and posterior segment vitrectomy.

8. Brief Summary of Nonclinical Tests and Results

Safety tests of the Stellaris® Vision Enhancement System have demonstrated its compliance with applicable requirements of the following standards:

- IEC 60601-1: Edition 3: 2007 Medical Electrical Equipment – Part 1: General Requirements for Safety
- IEC 60601-1-2: Edition 3:2007-03 Medical Electrical Equipment – Part 1: General Requirements for Safety 2. Collateral Standard: Electromagnetic Compatibility – Requirements and Tests

Software changes were verified and validated in accordance with the Bausch & Lomb software quality procedures which comply with EN62304.

The Stellaris® Vision Enhancement System passed all of the above tests with no exceptions. This testing demonstrates that the functional requirements have been met and that the modified device is equivalent to the predicate device.

9. Conclusion

The Stellaris® Vision Enhancement System shares identical indications for use, similar design features, and functional features with, and thus is substantially equivalent to, the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 14, 2014

Bausch & Lomb, Inc.
% Mr. Timothy W. Capehart
Manager of Regulatory Affairs, Equipment and Instruments
3365 Tree Court Industrial Blvd.
St. Louis, MO 63122

Re: K133242
Trade/Device Name: Stellaris® Vision Enhancement System
Regulation Number: 21 CFR 886.4670, 21 CFR886.4150
Regulation Name: Phacofragmentation system
Regulatory Class: Class II
Product Codes: HQC, HQE
Dated: December 13, 2013
Received: December 16, 2013

Dear Mr. Capehart:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: Registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K133242

Device Name: Stellaris® Vision Enhancement System

Indications for Use :

The Bausch & Lomb Stellaris® Vision Enhancement System device is intended for the emulsification and removal of cataracts, anterior and posterior segment vitrectomy. The system is designed for use in both anterior and posterior segment surgeries. It provides capabilities for phacoemulsification, irrigation/aspiration, bipolar, coaxial, and bipolar coagulation, vitrectomy, viscous fluid injection/removal and air/fluid exchange operations. Use only Bausch & Lomb disposable packs and handpieces designated for use with the system.

Prescription Use ___√____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Bradley S. Cunningham -S
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